



To: WVU Clinical Research Community

From: Clay Marsh
Chancellor & Executive Dean for Health Sciences

Fred King
Vice President for Research

RE: Clinical Study Agreement Services

Date: April 15, 2024

Clinical research at West Virginia University has increased significantly over the last 6 years as WVU has become a trusted clinical partner for research studies. Expanding clinical research aligns with WVU's land grant mission of serving the people of our state and bringing cutting-edge clinical studies to our residents. The launch of the Clinical Trials Center of Excellence in 2017 was our first formalized step in ensuring comprehensive support for clinical trials. As a next step, we are launching a reimagined contract negotiation service to support clinical trials, observational studies, and big data research studies.

A group specializing in clinical trials agreements will provide clear and transparent service for clinical study agreement negotiation, including clinical trials agreements and data use agreements. This team is part of WVU's overall support for researchers operating under the Clinical Trials Center of Excellence directed by Associate Vice President for Clinical and Translational Science, Dr. Sally Hodder. It reports up through the VP of Research, Fred King.

Beginning May 1, all negotiation for *new* clinical study agreements, new amendments to clinical study agreements, and clinical data use agreements will be routed through this new office designed specifically to process clinical agreements in a timely and efficient manner. The process is linked to the Clinical Trials Center of Excellence registration and will be managed in WVU+kc until the Huron electronic research administration system, WRAP, becomes available in the future. Any previously existing agreements that were submitted for negotiation prior to April 2024 will remain with their originally assigned negotiator for consistency.

A dedicated team of specialists, including a director of clinical trial agreements, Paul Fetty – paul.fetty@hsc.wvu.edu, a contract agreement specialist, Jillian Corbett – jillian.corbett@hsc.wvu.edu, and concierge, Caitlin Regner – Caitlin.regner@mail.wvu.edu, is ready to provide excellent customer service to clinical investigators and their teams. The team works closely with WVU Medicine, WVU Research Office of Sponsored Programs, and the WVU General Counsel's Office to ensure alignment and efficiency.

Several information sessions on this new resource will be held for investigators and their research teams. However, if you have inquiries regarding these changes, please contact the team members listed above.